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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,292	07/03/2001	Michele Amouyal	1231-01	2241

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IP DEPARTMENT OF PIPER RUDNICK LLP
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EXAMINER

SIEW, JEFFREY

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 06/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/898,292

Applicant(s)

AMOUYAL, MICHELE

Examiner

Jeffrey Siew

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 11-26 is/are pending in the application.
- 4a) Of the above claim(s) 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 11-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 11-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. This application contains claims 24-26 are drawn to an invention nonelected with traverse in Paper No. 16. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

2. The response filed 5/6/03 regarding the art rejections have been fully considered and deemed not persuasive. The response argues that Sobczak et al teach linear DNA not circularization of DNA and they teach concatemers which are linear. The response also points to the specification where the applicant illustrate that H1 alone does not yield good results when acting as a compaction agent. Sobczak et al do state they are working with linear DNA but in the production of **circularized vector particularly PBR322** (see introduction first paragraph “insertion of foreign DNA into plasmid requires not only intermolecular but also intramolecular ligation of DNA to allow circularization”). In the production of these circularization Sobczak et al examine these two processes and the effect of certain agents in particular histone, PEG and salts. The rejection is based on 102. The response argues that histone may not work effectively as a compaction agent. However, the claim steps still would reasonably read on Sbozcak who teach the addition of various agents which affect the circularization of recombinant vectors. Moreover, the response states that Sbozcak do not test any transformation or characterization of recombinants. The 103 standard is not whether Sobcak et al did the testing but rather whether one of ordinary of skill would have been motivated to further take Sobczak et al's vectors and

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transform them into cells . One of ordinary skill in the art would have been clearly motivated apply Sobczak et al's teaching of successful ligation of vectors to transformation of cells as it was well known in the art and commonly practiced at the time the invention was made to create vectors to propagate foreign DNA in cells. Sobczak et al clearly teach the effect of histone on the fact that intramolecular ligation was inhibited which is the concatamerization and stimulated intermolecular ligation which is the ligation of foreign insert into vector to create the circularized vector (see page 382). The rejections are maintained.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11,14-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Sobczak et al (Eur. J. Biochem. Vol. 175 pp. 379-385 1988).

Sobczak et al teach preparing circular pBR322 vector with ligated EcoRI or HincII inserts and compaction agent histone H1 (see whole doc. esp. abstract and page 379). The HI was added to the mixture (see ligase assay). They also teach histone is added prior to ligase (see figure 5). They also teach addition of 4 core histones and also adding PEG and NaCl (see page 384).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sobczak et al (eur. J. Biochem. Vol. 175 pp. 379-385 1988) in view of Gaffney et al (US5,710,031 Jan,20, 1998).

The teachings of Sobczak et al are described previously.

Sobczak et al do not teach 10kb vectors or cloning.

Gaffney et al teach construction of 20-30 bp fragments into vector pVK100 and transferring to *E. coli* for later cloning and testing (see col. 16 lines 14-27).

One of ordinary skill in the art would have been motivated to combine Gaffney et al's recombinant vectors with Sobczak et al's ligation technique in order to promote the intermolecular ligation of fragment to vector. Sobczak et al's technique provides for increased ligation efficiency. It would have been prima facie obvious to apply Sobczak et al's ligation technique employing histones to Gaffney et al's large vectors in order to increase the ligation of large fragments into the pVK100 vector.

Moreover, it was well known and commonly practiced in the art to construct vectors and propagate the vectors in *E.coli* or competent cells for future cloning and analysis.

SUMMARY

4. No claims allowed.

CONCLUSION

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m.

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If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Monica Graves for Art Unit 1637 whose telephone number is (703)-306-2938.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER
6/15/03